

REMARKS

Reconsideration and allowance in view of the foregoing amendments and the following remarks are respectfully requested.

Claims 1-51 remain pending in the present application.

Minor informal changes were made to claim 22 for the purposes of readability. Applicant respectfully requests that the amendments to claim 22 be approved.

Claims 1-32 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 6,305,374 to Zdrojkowski et al. ("the '374 patent") in view of U.S. Patent No. 5,715,390 to Hoffman et al. ("the '390 patent"). Applicant respectfully traverses this rejection for the reasons presented below.

The Examiner correctly notes that the '374 patent pertains to a medical device - namely a device that delivers a bi-level pressure support therapy to a patient. However, contrary to the Examiner's suggestion, the '374 patent does not teach or suggest a method of upgrading such a device. The Examiner cites the Abstract of the '374 patent, which is reproduced below, as suggesting a method of upgrading a medical device:

An improved methodology and systems for delivery of breathing gas such as for the treatment of obstructive sleep apnea through application of alternating high and low level positive airway pressure within the airway of the patient with the high and low airway pressure being coordinated with the spontaneous respiration of the patient, and improved methods and apparatus for triggering and for leak management in such systems.

Applicant respectfully submits that nothing in the Abstract of the '374 patent teaches or suggests the concept of upgrading a medical device. If the Examiner continues to maintain that this patent teaches this concept, applicant respectfully requests the Examiner to specify the language or figures from this patent that support this conclusion.

The '390 patent is cited as teaching the remaining features of claim 1, such as the external access key, the external device that contains the external access key, and the comparing

of the external key with the internal key and subsequent upgrading of the medical device if these keys match. While the applicant does not admit that the '390 patent teaches these features, applicant first submits that the Examiner has failed to establish a suggestion to combine the features of the '390 patent into the teachings of the '374 patent.

The law requires that the requisite motivation for modifying a reference be seen from some teaching, suggestion, or inference in the prior art and not from applicant's disclosure. *Uniroyal, Inc. v Rudcan-Wiley, Corp.*, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988). Indeed, the Examiner bears the burden of establishing the existence of either 1) some objective teaching in the prior art or 2) knowledge generally available to one of ordinary skill in the art which would lead that individual to change the primary reference. *In re Jones*, 21 U.S.P.Q.2d 1941, 1943-44 (Fed. Cir. 1992). Section 103 does not allow the Examiner to engage in picking and choosing from the prior art only to the extent that it will support a holding of obviousness, while excluding parts of the prior art essential to the full appreciation of what the prior art suggests to one of ordinary skill in the art. *In re Wesslau*, 147 U.S.P.Q. 391 (C.C.P.A. 1975). As the CAFC has said, obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. *ACS Hospital Systems v. Montefiore Hospital*, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). There must be a suggestion in the art relied upon to use what one reference discloses in or in combination with the disclosure of the other reference or references relied upon by the Examiner. *In re Grabiak*, 226 U.S.P.Q. 870, 872 (Fed. Cir. 1986).

In rejecting claim 1, the Examiner has not satisfactorily explained what motivation exists in the prior art to combine the teachings of the '390 patent with that of the '374 patent. First, the Examiner's reliance on the Abstract of the '374 patent as providing this motivation appears to be misplaced for the reasons noted above. Second, the Examiner's stated motivation given on page 3, lines 9-12 of the March 21, 2006 Office Action fails to provide the missing suggestion. According to the Examiner, "...it would have been obvious for one of ordinary skill in the art to have modified the method of Zdrojowski with the aforementioned features from Hoffman with the motivation of providing a highly secure method of upgrading a

device, as recited in Hoffman, (Col. 36-38). This reasoning, however, fails to explain why a highly secure method of upgrading a medical device is even necessary. The Examiner appears to be drawing an inference that this would be desirable, but has not set forth any suggestion existing in the prior art in support of that inference.

Applicant submits that it appears that the Examiner is using an incorrect hindsight review of the prior art, using the present invention as an instruction manual or “template” to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This practice has been expressly prohibited by the Federal Circuit. For example, the Federal Circuit has held that “[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention.” *In re Fritch*, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992)(quoting *In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988)).

The invention that was made does not make itself obvious; that suggestion or teaching must come from the prior art. *See, e.g., Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 5 U.S.P.Q.2d 1434, 1438 (Fed. Cir. 1988)(it is impermissible to reconstruct the claimed invention from selected pieces of prior art absent some suggestion, teaching, or motivation in the prior art to do so); *Interconnect Planning Corp. v. Feil*, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985)(it is insufficient to select from the prior art the separate components of the inventor’s combination, using the blueprint supplied by the inventor); *Fromson v. Advance Offset Plate, Inc.*, 225 U.S.P.Q. 26, 31 Fed. Cir. 1985)(the prior art must suggest to one of ordinary skill in the art the desirability of the claimed combination).

The Examiner also appears to recognize that there may be not motivation or suggestion to combine the teachings of the ‘390 patent with that of the ‘374 patent, because the Examiner also states on page 3, lines 14-15, of the March 21, 2006 Office Action that “...the concept of securely upgrading a medical device or controller in Hoffman can be applied to variety of devices and machines.” However, it is well settled that there must be some reason, suggestion, or motivation from the prior art, as a whole, for a person of ordinary skill in the art to have modified the reference in the manner suggested by the Examiner. The mere fact that the

prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *See, In re Fritch*, 972 F.2d 1260, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992). The fact that elements of the claimed invention exist in the known art does not by itself provide the motivation to make the claimed invention. *See, e.g., In re Newell*, 13, U.S.P.Q.2d 1248 (Fed. Cir. 1989).

Applicant further notes that the teachings of the '390 patent apply to the art of electrical power meters, which are classified in US. patent class 395. The present invention, however, pertains to a medical device, which is classified in patent class 128. Thus, there is a question as to whether these references are from sufficiently analogous art to allow them to be combined. Two criteria have evolved for determining whether prior art is analogous: 1) whether the art is from the same field of endeavor, and 2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.... A reference is reasonably pertinent if...it is one which, because of the matter with which it deals, logically would have commended itself to the inventor's attention in considering the problem. *In re Clay*, 23 U.S.P.Q.2d 1058, 1060-61 (Fed. Cir. 1992).

Applicant submits that the electrical power meter art and the medical device art not the same field of endeavor. Thus, the first step in the analogous art determination is not met. Applicant submits that one skilled in the art of medical devices (class 128) would not have logically turned to the electrical power art (class 395) for solutions to problems existing the medical art. Thus, the second step of the analogous art determination is not met. The Examiner takes the position that, "the concept ... to upgrade an electric meter is the similar concept of the claimed invention". Page 3, lines 13-15, of the March 21, 2006 Office Action. This statement fails to explain why one skilled in the art of medical devices would consider it logical to look to the field of electrical power meters to solve problems associated with medical devices. It also again appears to be a hindsight review of the prior art, looking for references that can be combined to achieve the present invention, using the present invention as a guideline for putting these references together.

For the reasons presented above, applicant respectfully submits that independent claim 1 is not rendered obvious by the cited references. In addition, claims 2-10 are also not rendered obvious due to their dependency from independent claim 1. Independent claim 12 is also not rendered obvious by the cited references for the reasons presented above with respect to claim 1. Likewise, claims 13-21 are not rendered obvious due to their dependency from independent claim 12.

With respect to independent method claim 22, the comments noted above with respect to claim 1 are equally applicable. In addition, the Examiner appears to misreading the '374 patent. For example, the Examiner alleges that the '374 patent teaches providing "an internal access key ... associated with each set of operating features of the medical device (Zdrojkowski: Col. 5, ln. 48-57)." Page 6, lines 6-7, of the March 21, 2006 Office Action. Applicant respectfully disagrees that the '374 patent teaches these features. Column 5, lines 48-57, of the '374 patent are reproduced below:

"The pressure controller 26 is operative to control the pressure of breathing gas within the conduit 20 and thus within the airway of the patient. Pressure controller 26 is located preferably, although not necessarily, downstream of flow generator 14 and may take the form of an adjustable valve which provides a flow path which is open to the ambient atmosphere via a restricted opening, the valve being adjustable to maintain a constant pressure drop across the opening for all flow rates and thus a constant pressure within conduit 20."

Applicant respectfully submits that nothing in this portion of the '374 patent teaches or suggests the concept of upgrading a medical device or using an internal access key associated with each set of operating features for that device. If the Examiner continues to maintain that this patent teaches this concept, applicant respectfully requests the Examiner to specify the language or figures from this patent that support this conclusion.

For the reasons presented above, applicant respectfully submits that independent method claim 22 is not rendered obvious by the cited references. In addition, claims 23-31 are also not rendered obvious due to their dependency from independent claim 22. Accordingly, applicant respectfully requests that the above rejection of claims 1-31 be withdrawn.

Claims 32-51 stand rejected under 35 U.S.C. § 103 as being unpatentable over the '374 patent in view of the '390 patent in further view U.S. Patent No. 6,094,702 to Williams et al. ("the '702 patent"). Applicant respectfully traverses this rejection for the reasons presented below.

In rejecting independent claim 32 the Examiner cites column 25, lines 2-6, of the '374 patent as teaching a method of upgrading a medical device. This portion of the '374 patent recites:

Finally, it is to be noted that the average leak rate whose calculation is described here was used initially in this algorithm in one of the conditions for initiating a breath trigger. The parameters used in the conditions for initiating a breath trigger thus can be continually updated, used to satisfy the breath trigger conditions, and then the successive breath triggers are used in turn to again update these parameters.

Applicant submits that this portion of the '374 patent refers to the technique by which triggering events are detected using the monitored condition of the patient. The monitored parameters, such as the rate of gas leak from system, can and are updated so that the system is taking into consideration the most up-to-date information when deciding whether a breath trigger condition exists. Applicant submits that upgrading or updating the parameter of a triggering algorithm is unrelated to the concept of upgrading a medical device using a key comparison process and for the purpose of changing the operating features or operating modes of the medical device.

In rejecting claim 32, the Examiner again combines the teachings of the '374 patent and the '390 patent. The reasons why these patents cannot be combined that were noted above with respect to the rejection of claim 1 are equally applicable to the rejection of claim 32. The additional citation to the '702 patent fails to provide the missing motivation to combine or to rectify the apparent use of hindsight to reconstruct the present invention from bits and pieces of the prior art.

For the reasons presented above, applicant respectfully submits that independent claim 32 is not rendered obvious by the cited references. In addition, claims 33-48 are also not

rendered obvious due to their dependency from independent claim 32. Independent claim 49 is also not rendered obvious by the cited references for the reasons presented above with respect to claim 32. Likewise, claims 50-51 are not rendered obvious due to their dependency from independent claim 49. Accordingly, applicant respectfully requests that the above rejection of claims 32-51 be withdrawn.

All objections and rejections have been addressed. It is respectfully submitted that the present application is in condition for allowance and a Notice to the effect is earnestly solicited.

Respectfully submitted,

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